STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: TENNESSEE

LIMITATION ON AMOUNT, DURATION AND SCOPE OF MEDICAL CARE AND SERVICES PROVIDED

Pursuant to 42 U.S.C. Section 1396r-8 the state is establishing a preferred drug list with prior authorization for drugs not included on the preferred drug list. Prior authorization will be provided with a 24-hour turn-around from receipt of request and a 72-hour supply of drugs in emergency situations.

Prior authorization will be established for certain drug classes, particular drugs or medically accepted indication for uses and doses.

The state will appoint a Pharmaceutical and Therapeutic Committee or utilize the drug utilization review committee in accordance with Federal law.

(11) When a provider with prescribing authority prescribes a covered medication for a TennCare member, and the prescription is presented at a pharmacy that participates in the TennCare program, the member is entitled to either:

(a) The drug as prescribed, if the drug is covered by TennCare and does not require prior authorization; or

(b) The drug as prescribed, if the prescribing provider has obtained prior authorization or established the medical necessity for the medication; or

(c) An alternative medication, if the pharmacist consults the prescribing provider when the member presents the prescription to be filled, and the provider prescribes the substituted drug; or

(d) An emergency supply of the prescribed drug, if the pharmacist is unable, when the member presents the prescription to be filled, to obtain authorization from either TennCare or the designated TennCare point-of-sale (POS) pharmacy claims processor to fill the prescription as written or the prescribing provider's authorization to substitute an alternative medication. If the member does not receive the medication of the type and amount prescribed, the pharmacist shall immediately provide written notice of the right to appeal, including the right to request continuation of services pending appeal, as required by the *Grier* Revised Consent Decree. The member's entitlement to receive an emergency supply of the prescribed drug is subject to the provisions as set out below.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: TENNESSEE

LIMITATION ON AMOUNT, DURATION AND SCOPE OF MEDICAL CARE AND SERVICES PROVIDED

(12) The member is entitled to an emergency supply of the prescribed drug provided that:

(a) The manufacturer has a rebate agreement and the medication is not classified by the FDA or regarded by CMS to be less than effective (DESI, LTE or IRS drug); or

(b) The medication is not a drug in a non-covered TennCare therapeutic category or class of drugs or products such as: agents used for anorexia, weight loss or weight gain, agents used to promote fertility, agents not listed on the TennCare preferred drug list used for the symptomatic relief of cough and colds, agents used for cosmetic purposes or hair growth, agents used to promote smoking cessation, agents not listed on the TennCare drug preferred drug list which are prescription vitamins and mineral products, agents not listed on the TennCare preferred drug list which are nonprescription (over-the-counter) products and drugs, agents not listed on the TennCare preferred drug list which are barbiturates or benzodiazepines. TennCare will exclude from coverage all of the allowable exclusions described above, with the exception of benzodiazepines and barbiturates. TennCare will cover a limited list of nonprescription drugs used to treat the symptoms of coughs and colds; or

(c) Use of the medication has not been determined to be medically contraindicated because of the member's medical condition or possible adverse drug interaction; or

(d) The prescriber did not prescribe a total quantity less than an emergency supply, in which case the pharmacist must provide a supply up to the amount prescribed.

(13) There are some cases in which it is not feasible for the pharmacist to dispense an emergency supply because the drug is packaged by the manufacturer to be sold as the original unit or because the usual and customary pharmacy practice would be to dispense the drug in the original packaging (inhalers, eye drops, topicals, etc.). When coverage of an emergency supply of a prescription would otherwise be required and when, as described above, it is not feasible for the pharmacist to

dispense an emergency supply, it shall be the responsibility of TennCare to provide coverage for either the emergency supply or the usual dispensing amount, whichever is greater.

(14) Pharmacies should bill prescriptions for TennCare members with other third party insurance to the appropriate third party payer (primary insurer) and bill any applicable copays for covered drugs to TennCare.

(15) Covered drugs under the TennCare Pharmacy Program shall be limited to:

(a) Those legend drugs covered under the Medicaid Drug Rebate Program as described in Section 1927 (k) of the Social Security Act and outlined in the TennCare Pharmacy Program Preferred drug list; and

(b) Non-legend drugs which are listed on the covered OTC drug list; and

(c) Legend and non-legend drugs which are covered and prescribed by an authorized prescriber; and

(d) Those drugs which are not included in the list of excluded therapeutic categories or classes contained in Section 1927(d) of the Social Security Act (listed above in (12)(b); and

(e) Those drugs not considered to be DESI, less-than-effective (LTE) or identical, related or similar (IRS) to DESI drugs.

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STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: TENNESSEE

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES – OTHER TYPES OF CARE

12. Prescribed drugs, dentures, and prosthetic devices, and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

12.a. Prescribed drugs

(1) Payments for legend drugs authorized under the program may be made through a contract with one or more pharmacy benefits vendors or directly participating pharmacies. Payments shall include:

(a) Payments for the cost of legend drugs will be in conformity with 42 CFR 447.331 and will be the lesser of:

- Average Wholesale Price AWP minus 13%, as described by First Data Bank, plus the dispensing fee, except for DEA Schedule II drugs which shall be one hundred percent (100%) of the Average Wholesale Price, plus the dispensing fee; or
- Maximum allowable cost (MAC), as published in the TennCare Pharmacy Program's Pharmacy Manual MAC price list, plus the dispensing fee; or
- The federal upper limit of the drug, if any, plus the dispensing fee; or
- The pharmacy provider's usual and customary charges to the cash-paying public.

(2) Payment for any covered non-legend drug or product, authorized under the program, shall be the lesser of:

(a) The provider's usual and customary charges to the cash-paying public; or

(b) Maximum allowable cost (MAC), as published in the TennCare Pharmacy Program's Pharmacy Manual MAC price list or the TennCare over-the-counter (OTC) preferred drug list plus the dispensing fee.

(3) The dispensing fee is established at $2.50 for each prescription, except for long term care (nursing home) pharmacy claims, where, when the days supply is

greater than twenty-eight (28) days, the pharmacy provider shall receive a fee of $5.00.

(4) Long term pharmacy claims must only be billed once per month, but must be filled in seven (7) day supplies and the same drug, dispensed for the same patient, in a particular month shall receive only one dispensing fee. All pharmacy providers, except pharmacy providers serving a long term care TennCare member in a nursing home, shall bill the TennCare program for all drugs utilized on a maintenance basis in thirty-one (31) days quantities or the nearest stock packet size (if so dispensed) as the pharmacist desires.

(5) All pharmacy providers must bill all appropriate pharmacy claims to the designated TennCare point-of-sale (POS) pharmacy claims processor or pharmacy benefits manager (PBM) or pharmacy benefits administrator (PBA) online using the actual National Drug Code (NDC) for the actual package size of the drug dispensed to the member. In the event that a drug manufacturer disputes a rebate payment to the state because a pharmacy billed the wrong NDC number, that claim may be voided and any payments to that pharmacy will be recouped so that the claim may be re-billed appropriately.

(6) Pharmacies licensed in Tennessee by the Tennessee Pharmacy Board, and all pharmacies outside Tennessee which are licensed under the laws of their respective states or when appropriate, also licensed in Tennessee, are eligible to participate in the TennCare program. The pharmacy must agree in writing, by signing the TennCare Participating Pharmacy Agreement, to provide services to eligible TennCare members in compliance with all rules, published state and federal regulations, the agreement, TennCare policies, any applicable court orders or consent decrees and the TennCare Pharmacy Manual. The pharmacy agrees to accept the payment authorized under the TennCare program for dispensing drugs when prescribed by a licensed prescriber acting under the authority granted by such licensure, as payment in full, and to bill the prescription in accordance with TennCare guidelines.

(7) A maximum of thirty-one (31) days supply and five (5) refills within six (6) months from the date of service on the original claim will be allowed for all covered drugs if authorized by a prescribing practitioner. Refills are covered only when filled according to the regulations, rules and laws set by the Tennessee Board of Pharmacy. The online, point-of-sale (POS) pharmacy claims

processing system will deny any refills (or new prescriptions for the same drug) if submitted before a time period whereby seventy-five percent (75%) of the original days supply could be consumed by the member. TennCare publishes a list of maintenance drugs which may be filled for three (3) month supplies or 100 units, whichever is greater. Long term care pharmacy providers may bill a thirty-five (35) day supply of covered medication for TennCare members residing in a nursing home.

(8) Participating Pharmacy Provider Incentive Payments. On or after July 1, 2003, TennCare will implement a single, statewide preferred drug list (PDL) that will define the pharmacy benefit for all TennCare members. Participating pharmacy providers will submit all TennCare pharmacy claims to the TennCare PBM/PBA for adjudication. Participating pharmacy providers are required to contact the prescriber in the event a TennCare member presents a prescription for a non-preferred or non-covered drug and request or suggest a covered alternative medication to replace the original (non-covered) prescription. After implementation of the first three phases of the PDL, TennCare will review pharmacy claims data every six months to analyze every participating pharmacy provider's compliance with the PDL. In the event a participating pharmacy provider maintains a ninety percent or greater PDL compliance rate for that six month time period, the participating pharmacy provider will be paid ten cents ($0.10) for every TennCare prescription that participating pharmacy provider dispensed during that six-month time period. If any participating pharmacy provider is found to have violated the *Grier* Revised Consent Decree during that six-month time period, however, that participating pharmacy provider may forfeit all incentive payments for the period and be subject to sanctions.

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STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: TENNESSEE

LIMITATION ON AMOUNT, DURATION AND SCOPE OF MEDICAL CARE AND SERVICES PROVIDED

12. Prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist.

12.a. Prescribed drugs

(1) Prescription outpatient drugs of any manufacturer which has entered into and complies with an agreement under Section 1927(a) of the Social Security Act will be a covered benefit for all TennCare members when prescribed by an authorized licensed prescriber, unless coverage is excluded or otherwise restricted by TennCare in accordance with the following:

(a) As provided by Section 1927(d) of the Social Security Act, hereinafter referred to as the Act, the following drugs or classes of drugs or their medical uses are allowed to be excluded from coverage or otherwise restricted: agents when used for anorexia or weight control, agents when used to promote fertility, agents when used for cosmetic purposes or hair growth, agents when used for the symptomatic relief of coughs and colds, agents when used to promote smoking cessation, nonprescription drugs, covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests and monitoring services be purchased exclusively from the manufacturer or its designee, barbiturates, benzodiazepines, and drugs described in Section 107(c)(3) of the Drug Amendments of 1962 and identical, similar, or related drugs (DESI, IRS and LTE) as described in Section 1903(i)(5) of the Social Security Act. TennCare will exclude from coverage all of the allowable exclusions described above, with the exception of benzodiazepines and barbiturates. TennCare will cover a limited list of nonprescription drugs used to treat the symptoms of coughs and colds.

(2) No payment will be made for an innovator multiple source drug (brand name drug) if, under applicable State law, a less expensive multiple source drug could have been dispensed, but only to the extent that such amount exceeds the upper payment limit for such multiple source drug. In the event a prescriber indicates on the face of the prescription ("dispense as written") that he/she is requiring a specific brand name drug be dispensed for a specific TennCare member or if a TennCare member appeals coverage of a generic drug and the appeals process

results in approval of a specific brand name drug, then the reimbursement methodology for that prescription will the same as that for innovator single source drugs covered under the TennCare pharmacy program.

(3) A prior approval system for drugs requiring prior authorization will comply with Section 1927 of the Act and be administered by the pharmacy benefits manager (PBM) or pharmacy benefits administrator (PBA) under contract to TennCare to provide those services. The prior authorization process provides for a turn-around response by either telephone or other telecommunications device within twenty-four hours of receipt of a prior authorization request. In emergency situations, providers may dispense at least a seventy-two hour supply of medication.

(4) Participating pharmaceutical manufacturers will be furnished drug rebate utilization data and allowed to audit this data as set forth and according to the Centers for Medicare and Medicaid Services (CMS) guidelines pursuant to the Act.

(5) As provided by the Act, a new drug manufactured by a company which has entered into a rebate agreement may be covered subject to prior approval, unless the drug is subject to the allowable exclusion categories provided by the Act.

(6) As specified in section 1927(b)(3)(D) of the Act, notwithstanding any other provision of law, information disclosed by manufacturers shall not be disclosed by the State in a form which discloses the identity of a specific manufacturer or prices charged for drugs by such manufacturers, except as the Secretary determines to be necessary and/or to permit the Comptroller General to review the information provided.

(7) Separate agreements between the State and the manufacturers require CMS authorization. The State has CMS authorization for the collection of supplemental rebates that are negotiated with pharmaceutical manufacturers pursuant to the TennCare preferred drug list (PDL) as required by the Act. TennCare will report supplemental rebates from separate agreements to CMS.

(8) The state is in compliance with Section 1927 of the Social Security Act. The state will cover drugs of federal rebate participating manufacturers. The state is

in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers can audit utilization data. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.

The state will be negotiating supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates.

A rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on August 13, 2003 and entitled, "State of Tennessee Supplemental Rebate Agreement," has been authorized by CMS.

Supplemental rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.

All drugs covered by the program, irrespective of a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.

(9) Pharmacies shall collect all applicable TennCare-required copays from TennCare members. Services cannot be denied to any eligible recipient because of the individual's inability to pay the co-payment. This requirement does not apply to an individual who is able to pay. An individual's inability to pay does not eliminate his or her liability for the co-payment charges. A recipient is deemed unable to pay the co-payment if the recipient states to the pharmacist that he or she cannot pay.

(10) In accordance with the provisions of the Act, TennCare will begin the development and implementation of a preferred drug list (PDL) on July 1, 2003. TennCare will move to a single, statewide preferred drug list (PDL) for the entire pharmacy program. Furthermore, TennCare will employ a single pharmacy benefits manager (PBM) to process all TennCare pharmacy claims and respond to all prior approval requests.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: TENNESSEE

LIMITATION ON AMOUNT, DURATION AND SCOPE OF MEDICAL CARE AND SERVICES PROVIDED

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